Main Document

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Approved by

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Director

NOAA Global Monitoring Division

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GMD Quality Manual for Measurement Services

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1.0 Introduction

The provision of measurement services, which includes calibration services and certified reference materials, is an element of the work carried out by the Global Monitoring Division (GMD) of the Earth System Research Laboratory, National Oceanic and Atmospheric Administration (NOAA) in support of its Central Calibration Laboratory (CCL) roles within the World Meteorological Organization Global Atmospheric Watch (WMO/GAW). Our goal is to provide services essential to the operation of WMO/GAW measurement programs for greenhouse gases (GHG) and other related tracers. The GMD Quality Management System comprises policies and procedures that GMD follows in support of WMO/GAW calibration activities (see also http://www.esrl.noaa.gov/gmd/ccl/).

1.1 Commitment to quality

GMD has served as a Central Calibration Laboratory of WMO/GAW for CO₂ since 1995, and for several other greenhouse gases at later dates. GMD has championed the use of high quality reference gases (reference materials) for many years, and has strived to ensure that GMD measurements and those within WMO/GAW are linked to traceable, reliable reference materials that are internationally accepted. A commitment to quality lies at the heart of long-term records produced by GMD, and extends to GMD CCL roles. The international standard ISO/IEC 17025 and relevant requirements of ISO Guide 34 specify the general requirements for the competence to carry out tests and/or calibrations. It is GMD policy to conform to ISO/IEC 17025 and ISO Guide 34 to the extent allowed by statute and regulation, considering also the needs of WMO/GAW partners.

1.2 Scope

The quality management system described in this manual covers measurement (calibration and reference material) services provided to customers within WMO/GAW programs and internal to GMD. Services described by this manual and supporting documents are limited to the functions of the CCLs, and pertain only to calibration and reference materials for CO₂, CH₄, CO, N₂O, and SF₆.

1.3 Format of quality manual

The GMD Quality Manual (QM) describes GMD policies and procedures related to the objectives described in (1.2). Details for each calibration service (CO₂, CH₄, CO, N₂O, SF₆), the preparation of compressed gas standard mixtures (reference materials), and the primary standards upon which calibrations are based are documented as Technical Procedures (Table 1).

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Table 1: List of sub-level documents

Document Name	Subject	Type
TP_primary_manometer.docx	manometric primary standards (CO ₂)	technical procedure
TP_primary_gravimetry.docx	gravimetric primary standards	technical procedure
TP_analysis_CO2.docx	CO ₂ analysis	technical procedure
TP_analysis_CH4.docx	CH ₄ analysis	technical procedure
TP_analysis_N2O.docx	N ₂ O analysis	technical procedure
TP_analysis_SF6.docx	SF ₆ analysis	technical procedure
TP_analysis_CO.docx	CO analysis	technical procedure
TP_reference_materials.doc	reference materials	technical procedure

2.0 Informative References

Federal Information Security Management Act (FISMA) 2002;

see http://csrc.nist.gov/groups/SMA/fisma/overview.html

GAW Report No. 186: 14th WMO/IAEA meeting of experts on carbon dioxide, other greenhouse gases and related tracers measurement techniques, (Helsinki, Finland, 10-13 September 2007), Geneva, Switzerland, 2009.

GAW Report No. 194: 15th WMO/IAEA meeting of experts on carbon dioxide, other greenhouse gases and related tracers measurement techniques, (Jena, Germany, 7-10 September 2009), Geneva, Switzerland, 2011.

GAW Report No. 206: 16th WMO/IAEA meeting of experts on carbon dioxide, other greenhouse gases and related tracers measurement techniques, (Wellington, New Zealand, 25-28 October 2011), Geneva, Switzerland, 2012.

GAW Report No. 213: 17th WMO/IAEA meeting of experts on carbon dioxide, other greenhouse gases and related tracers measurement techniques, (Beijing, China, 10-13 June 2013), Geneva, Switzerland, 2014. http://www.wmo.int/pages/prog/arep/gaw/documents/Final GAW 213 web.pdf

GMD Website: http://www.esrl.noaa.gov/gmd/ccl/

ISO Guide 31:2000 Reference materials – Contents of certificates and labels

ISO Guide 34:2009 General requirements for competence of reference material producers.

ISO/IEC 17025:2005 General requirements for the competence and testing and calibration laboratores

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JCGM 100:2008 Evaluation of Measurement Data – Guide to the Expression of Uncertainty in Measurement (ISO GUM 1995 with minor corrections), Joint Committee for Guides in Metrology (2008); http://www.bipm.org/utils/common/documents/jcgm/JCGM 100 2008 E.pdf

JCGM (2012), International vocabulary of metrology — Basic and general concepts and associated terms (VIM), JCGM 200:2012 (JCGM 200:2008 with minor corrections).

Letter of Agreement and Annex to the Letter of Agreement between WMO and NOAA/ESRL/GMD, signed 23 April 2010.

Mutual Recognition Arrangement – Mutual recognition of national measurement standards and calibration and measurement certificates issued by national metrology institutes, Comité international des poids et mesures (CIPM) Paris, 14 October 1999, www.bipm.org/utils/en/pdf/mra.pdf.

3.0 Terms and definitions

analyst: In analytical chemistry, an analyst is one who performs an analysis or a given part of a chemical measurement process; when used in the GMD quality document this term refers to a GMD technical staff member qualified to perform a specific measurement process or part thereof.

calibration: Operation that, under specified conditions, in a first step, establishes a relation between the quantity values and corresponding indications (each with measurement uncertainties) and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication. (from JCGM 200:2008, 2.39)

certified reference material: A reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

control standard: Any standard or material used to monitor the performance of a calibration system. A control standard could be a well-characterized gas standard (for gas analysis), or a well characterized object (for mass determination).

certificate: A document produced by GMD to report the measurement results and uncertainties associated with analytical services and GMD-supplied reference materials.

complaint: Any expression of dissatisfaction or concern made to an organization by, or on behalf of, an individual client – including government agencies – group or member of the public, related to the organization's products or services, or the complaints handling process itself.

ELOG: An electronic record keeping system used to record information pertaining to the operation and maintenance of analytical systems, software updates, and customer feedback.

gas standard: A cylinder of compressed gas (gas mixture) with mole fractions determined by

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primary means (see primary standard), or by analytical comparison to higher-level standards. For the purposes of this QM, all reference materials are gas standards.

GGMT: Greenhouse Gas and Related Measurement Techniques. This acronym refers to meetings that occur every 2 years, organized by WMO/GAW. These meetings focus on technical aspects of measurement and calibration and are central to the planning and operation of WMO/GAW Central Facilities, such as Central Calibration Laboratories. The acronym also refers to an email list of WMO/GAW scientists, and is used to communicate issues related to calibration scales and capabilities.

GMD Intranet: GMD internal data access or data storage services that include capabilities for access control and archiving of GMD documents.

GMD method: For the purposes of this QM, a GMD method is one that is documented in a technical procedure and validated by acceptable methods.

group leader: The highest ranking manager/scientist designated by the Director in the specialized research groups of GMD.

management: A general term to describe the next higher level of personnel management in GMD. Because many operational decisions pertaining to analysis and calibration will be made at the Technical Lead level, decisions that require management approval will be made at one or more levels above the TL.

measurement: Process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity. (JCGM 200:2008, 2.11)

measurement uncertainty: Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used. (JCGM 200:2008, 2.26)

metrological traceability: Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty. (JCGM 200:2008, 2.41)

primary standard: A measurement standard established using a primary reference measurement procedure, or created as an artifact, chosen by convention.

project coordinator (PC): A GMD staff member with responsibility for tracking a calibration or reference material project from start to finish. The PC is responsible for communicating requirements to the appropriate analysts. The PC is the primary customer contact. A deputy PC (DPC) may be designated.

quality system (QS): The organizational structure, responsibilities, procedures, and processes for implementing quality throughout the laboratory.

reference material: A material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process. (JCGM 200:2008, 3.6)

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Sales Fixed Fee Memorandum of Understanding (SFF MOU): An agreement between GMD and a customer in which terms and conditions relating to calibration services or reference materials are defined.

target mole fraction: A fixed goal for the mole fraction of a particular component in a reference material.

technical procedure (TP): A compilation of steps or actions associated with a specific task.

technical lead (TL): GMD member responsible for overseeing the technical aspects of calibration measurement or reference materials. GMD staff may assume multiple roles (TL, PC, analyst).

valid range: The mole fraction range for which the method is valid (WMO/GAW scale). The method may, in fact, be valid outside the specified range, but the extended validity may not be extensively documented.

4.0 Management requirements

4.1 Organization

NOAA/ESRL's Global Monitoring Division (formerly CMDL) of the National Oceanic and Atmospheric Administration conducts sustained observations and research related to source and sink strengths, trends and global distributions of atmospheric constituents that influence climate, contribute to depletion of the global ozone layer, and affect baseline air quality.

GMD accomplishes this mission primarily through long-term measurements of key atmospheric species at sites spanning the globe, including four Baseline Observatories. These key species include carbon dioxide, carbon monoxide, methane, nitrous oxide, surface and stratospheric ozone, halogenated compounds including CFC replacements, hydrocarbons, sulfur gases, aerosols, and solar and infrared radiation.

The measurements are of the highest quality possible, and document global changes in key atmospheric species. Research programs in key regions, utilizing an array of platforms including aircraft, balloons, ocean vessels and towers, complement the land-based information.

GMD data are used to assess climate forcing, ozone depletion and baseline air quality, to develop and test diagnostic and predictive models, and to keep the public, policy makers, and scientists abreast of the chemical and radiative state of the atmosphere.

GMD's vision and mission support the broader objectives of NOAA's Strategic Plan and are aligned with the vision and mission of the Office of Oceanic and Atmospheric Research (OAR).

ESRL/GMD's monitoring and research generally fall under the NOAA Strategic Plan Element to "Predict and Assess Decadal to Centennial Change" although much of the research at ESRL/GMD is relevant to other time scales included in the Strategic Plan. For

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example, interannual variations in the carbon dioxide growth rate are of major importance in studying carbon dioxide sources and sinks. Interannual climate variations, such as those caused by the El Niño phenomenon, have an effect on sources and sinks of climatically important gases.

Objectives under the NOAA Decadal to Centennial Change Element applicable to GMD are:

- Characterize the Forcing Agents of Climate Change
- Ensure a Long-Term Climate Record
- Guide the Rehabilitation of the Ozone Layer
- Provide the Scientific Basis for Improved Air Quality

Preeminent performance in these programs will allow realization of <u>GMD's VISION</u>:

A laboratory that serves society by providing the best possible information on atmospheric constituents that drive climate change, stratospheric ozone depletion, and baseline air quaility.

In all its activities, GMD emphasizes performance consistent with its CORE VALUES:

People: We respect, value and support each other in all our activities.

Integrity: We are objective, ethical, and honest.

Customer focus: We anticipate the needs of our customers and are committed to meeting or exceeding their expectations.

Excellence: We expect world-class performance and continuous improvement in all we do.

GMD is committed to providing a workplace that is free of undue commercial, financial, and other internal and external pressures that would adversely affect the fit-for purpose quality of the technical work of the division. High standards of ethical conduct, impartiality, objectivity and protection of confidential or proprietary information are vital to the success of GMD programs and required of all employees. Specific legal requirements and administrative guidance are provided to all employees in the publication Standards of Ethical Conduct for Employees of the Executive Branch

4.1.2 Physical Locations

GMD operations pertaining to measurement services are carried out in Boulder, Colorado. Relevant laboratories are housed within the David Skaggs Research Center (DSRC) building, at physical address 325 Broadway, Boulder, CO. Most reference materials are prepared at a field site in the Colorado mountains, known as Niwot Ridge, C1. The C1 facility is maintained by GMD and the University of Colorado.

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4.1.2 Organization Chart



4.2 Management System

GMD is committed to the formal Quality Management System outlined in the manual. GMD certifies its results for calibration services and reference materials. GMD does not certify reference materials or results for suitability for intended customer applications. GMD does not provide warranty for tests or analysis performed in a customer's laboratory using reference material obtained from GMD. It is GMD policy to provide calibration services in-house, without subcontracting. Subcontracting for reference materials may occur if directed by the customer.

The principal goal with respect to GMD calibration services is to provide calibration services at a level of quality consistent with the recommendations put forth and agreed upon by WMO/GAW

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participants (e.g. GAW Report No. 213, 2014), when possible. It is recognized that some WMO/GAW quality objectives are scientific "desirables", and may not be achievable with current equipment and methods.

To the extent permitted by resources, GMD agrees to participate in comparisons of WMO/GAW standards with those of National Metrology Institutes (NMIs). Special priority will be given to key comparisons conducted under the auspices of the Comité International des Poids et Mesures (CIPM).

4.2.1 Responsibilities, Authorities, Delegations

The GMD director is ultimately responsible for the quality of GMD calibration services. This responsibility is delegated to group chiefs and technical leads directly involved in providing measurement services. The GMD director is responsible for final approval of the GMD-QM, upon recommendation from technical leads and group chiefs involved in measurement services. Authority for approval of sub-level documents is delegated to group chiefs. The GMD Quality Manager is appointed by the GMD Director. Because the scope of this QM is limited to activities within one NOAA/ESRL division (GMD), the GMD QM may be a GMD staff member.

The GMD Quality Manager is Dr. Russell Schnell, Deputy Director of GMD

Responsibilities of the GMD Quality Manager

- 1) Organizes and schedules GMD quality management system assessments.
- 2) Oversees revisions of the GMD-QM, and assures that the GMD-QM is consistent with updates to ISO 17025 and ISO Guide 34.
- 3) Maintains document control for GMD-QM and sub-level documents.
- 4) Participates in GMD management reviews and semi-annual status review meetings.

4.3 Document control

4.3.1 Document approval and issue

The official version of GMD-QM is maintained on the GMD server [//emc3/CCL] and is readily available to all GMD staff. The official version of GMD-QM is a read/print-only document. An uncontrolled (read/print-only) copy of GMD-QM is available to anyone external to GMD on the GMD website [http://www.esrl.noaa.gov/gmd/ccl/]. This copy is updated (replaced) with each new and approved version of GMD-QM. GMD servers have appropriate security and backup systems in place. The GMD Quality Manager is responsible for assuring that the GMD-QM and sub-level documents available on internal and external websites are the official versions and copies thereof.

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4.3.2 Document Changes

After a revision of GMD-QM is approved as the official version, the GMD Quality Manager notifies all Technical Leads and Group Leaders that a revised version of GMD-QM is available on the GMD intranet. Document changes will be recorded using the MS Word tool "Track Changes". In the event that substantial changes are needed (updated method or instrument) a statement of substantial changes should be included. A copy of the official version as well as obsolete versions (clearly marked as obsolete) of GMD-QM documents shall be maintained on a separate backup system. These documents are official parts of the GMD QS documents.

4.4 Review of requests, tenders and contracts

All external requests for existing and routinely available measurement services offered by GMD are governed by policies specified in the Memorandum of Understanding (MOU). A Sales Fixed Fee MOU is established between GMD and the customer. The SFF MOU is reviewed annually by GMD staff and higher levels of NOAA.

4.4.1 Reference materials and calibration services

The procedure for creating and implementing a request for reference materials or calibration follows:

- 1. Customer makes initial contact through GMD ticket management system.
- 2. A project coordinator (PC) works with the customer to determine customer needs. The PC may supply the customer with a quotation.
- 3. The PC initiates a Memorandum of Understanding (MOU) for review and signature by the customer and NOAA. The customer sends two signed copies of the MOU (or one digitally signed copy by fax or email) to the PC. Once reviewed and accepted by GMD staff it is forwarded to NOAA administration for counter signature with one copy returned to the customer.
- 4. The PC prepares a work plan. The form of the work plan may vary, but should include a statement of work, calibrations required, ID numbers, and a target completion date.

 Official approval from higher levels of management is not required to initiate a work plan.
- 5. The PC is the primary contact for the customer while the work plan is in place.
- 6. The PC implements the work plan and communicates requirements to a DPC and/or analysts as necessary. This can be done through direct contact, email, or software designed for this purpose.
- 7. When the work plan is complete, the PC collects analytical results from a database or in consultation with one or more TLs or analysts. It is the responsibility of the analyst to ensure that data in the database are suitable for release to the customer.
- 8. The PC or DPC prepares an analysis certificate.
- 9. Certificates and calibrated items (gas cylinders) are sent to the customer.

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4.5 Subcontracting

4.5.1 Subcontracting of tests and calibrations

It is GMD policy that calibrations will not be subcontracted.

4.5.2 Subcontracting of reference materials

In some cases, customers may request reference materials prepared under subcontract. Customers will be notified of any relevant, known differences between subcontracted reference materials and those typically prepared by GMD personnel.

4.6 Procurement

Federal Procurement Policy and Regulations govern procurement of products and services from sources external to GMD. These policies are available at http://www.ago.noaa.gov/acquisition/regulation_and_guidance.html. In cases in which materials or services must meet special requirements to assure the quality of a service or reference material, these requirements are documented in GMD sub-level documents.

4.7 Service to the customer

GMD technical staff members who provide measurement services are expected to maintain communication with their clients. Normally, the PC will serve as the primary customer contact regarding specific orders. Issues may also be addressed by a TL or analyst, but the PC should be kept informed of all communication referring to specific orders. Communication can occur through a variety of means, including phone calls and email correspondence. Such communication is especially called for in the event of delays in delivery, anomalies regarding customer equipment, or unexpected issues arising during tests, measurements, or calibrations. Communication also may occur at WMO/GAW or other scientific meetings.

A questionnaire has been drafted and will be sent to customers requesting feedback.

4.8 Complaints

All staff members are responsible for assessing the significance of complaints, with guidance from Technical Leads or Project Coordinators, to ensure that the appropriate levels of GMD management are aware of the complaints and approve of the responses thereto. Resolution of complaints should be accomplished by the PC or TL and may involve higher levels of management when necessary. Complaints should be logged using the GMD ELOG system and include:

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- 1) the nature of the complaint, date received, name of person registering the complaint, GMD recipient, and initial response to the complainant
- 2) the final resolution of the complaint
- 3) a brief summary of all follow-up and the final communication with the complainant

4.9 Control of non-conforming work

491 General

Technical leads, analysts, and project coordinators share responsibilities for control of non-conforming work (i.e. calibration work that does not conform to GMD policies and procedures, or is otherwise deemed to be sub-standard). This includes evaluation of the significance of the non-conforming work. If a non-conformity is identified, the nature of the non-conformity should be documented and brought to the attention of the technical lead. Analysts, project coordinators, and technical leads should communicate collectively and assess the significance of the non-conformity, and agree on a plan to address the issue. The scope of the plan will depend on the significance of the non-conformity.

If there is evidence, derived from any source, including customer feedback, that results of a calibration are unreliable or if the technical requirements specified in the MOU are not met, the PC should be notified and discussion with the customer should ensue.

When non-conforming or substandard work is identified, the particulars should be recorded in the ELOG, and summarized in semi-annual status updates. At a minimum, the following should be documented:

- a) significance of the nonconforming work
- b) when the nonconformity was discovered and the impact on measurement services
- c) what was done to determine root cause
- d) correction efforts required or taken
- e) customer notification, if deemed necessary
- f) delay or work stoppage, if deemed necessary

Analysts have the authority to stop calibration activities in the event that nonconforming or substandard work is identified. If the work stoppage leads to a significant delay, as determined by the analyst, the technical lead should be notified. The group leader should also be notified if the situation results in severe disruption of calibration activities.

4 9 2 Interaction with customers

If it is known in advance that an item for calibration cannot be calibrated under normal conditions, the customer should be contacted to discuss the issue. The PC, in consultation with

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TPs or analysts, will then determine an alternate course of action and proceed with customer approval.

GMD is not responsible for non-conformities beyond GMD control. Possible reasons for non-conformance beyond GMD control include but are not limited to: a) inability to analyze a customer-supplied gas cylinder due to issues with gas connections, valves, etc. (b) erratic, unusually variable, or unstable behavior of trace gases in customer-supplied cylinders, and (c) inability to meet technical specifications due to unforeseen circumstances. With respect to reference materials, an inability to match all target mole fractions requested in the MOU is not considered non-conforming work. Customers will be notified in advance that gas blending is not exact, and that some mole fractions may differ from those desired. It is left to the PC to interact with the customer to reach agreement on targeted and resultant mole fractions.

4.9.2 Decisions on corrective action

If it is determined that nonconforming work is likely to reoccur, corrective and preventive action should be taken as specified in (4.11). The decision to implement minor corrective action may reside with analysts and technical leads. Major corrective actions, such as those requiring major purchases or procedure changes should involve the technical lead and group leader. For issues that cannot be resolved at the group leader level, the Quality Manager should be consulted.

4.10 Improvement

The software system used to log customer interactions can be used to analyze the effectiveness of the management system. This will occur in the context of internal audits and management reviews. Customer feedback will be an important input.

4.11 Corrective Actions

If non-conforming work is identified, the PC shall work with TLs or analysts to identify the root cause, and if warranted, notify the customer. The PC, analyst or TL (as specified in lower level documents) shall have authority to proceed with the work after corrective action is taken. Repeated occurrence of non-conformities should be addressed at the TL or group leader level. An internal audit may be initiated to address root cause.

If a non-conformity, for which GMD is responsible, is not discovered until after the customer received the standard and the non-conformity cannot be addressed to the customer's satisfaction in any other way, GMD will reanalyze the standard or attempt to provide a replacement standard at no cost to the customer.

Corrective actions will be documented in the ELOG system and summarized in semi-annual reports. Corrective action could lead to changes in the Quality Manual.

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4.12 Preventive Actions

It is GMD policy that all staff involved in calibration work use their analytical training and experience to identify needed improvements and/or potential sources of nonconformities (technical or managerial). Where identified, plans shall be initially discussed with Project Coordinators and Technical Leads, and ultimately could lead to changes in the Quality Manual. Actions should be documented in semi-annual status reports (4.14). Suggestions for actions can be discussed during semi-annual status review meetings, or brought to the attention of technical leads or group leaders.

4.13 Control of records

Customer records

Records of customer interaction are maintained using commercial software designed for this purpose (GMD ticket management system). Written interaction with customers (primarily by email) is logged and archived in a searchable database. Records of phone conversations with customers are entered, in summary form, in the database (typically by the PC).

Technical records

Data records pertaining to analytical results may include data stored during analysis, processing, and testing. Data may be generated and stored in digital form using commercial or custom software. Critical electronic records are backed up to secondary storage regularly. The analysts and TLs determine which electronic records are critical to calibration actions. Paper records (notebooks, log sheets, etc), if any, are kept in notebooks or binders. The identity of the analyst performing a procedure, measurement or test may be kept in electronic or paper form. Maintenance records for instruments and associated devices are stored in the ELOG. The ELOG is also used to record significant events related to the performance of analytical instruments.

Analysis Results

Analysis results are stored in a database. Analysis results are made available on the GMD website in anonymous form, searchable by cylinder number.

4.14 Status Reports and Internal Audits

Analysts and/or Technical Leads will prepare written summaries (Status Report) of activities every 6 months. Analysts, technical leads, and others will meet to review and discuss the Status Reports. A Summary Document, derived from the various Status Reports and related discussion, will be presented to the Quality Manager following the meeting. It is expected that corrective actions and preventive actions will be documented in the Status Reports.

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GMD will perform an internal audit at least every two years, at the direction of the GMD Quality Manager. To the extent possible, the audit will involve GMD personnel not involved in measurement services covered by this Quality Manual, personnel from NIST or another NOAA division on site, or personnel with technical knowledge of the WMO/GAW measurement program. An effort will be made to identify personnel with audit experience. Technical aspects of the audit may involve Technical Leads on a rotating basis, in which one or more Technical Leads perform a technical audit of the CCL function overseen by another TL. This may be necessary if available personnel with audit experience lack the technical knowledge to fully evaluate technical aspects of the program.

Results of the internal audit will be documented, and could lead to corrective action. A follow-up report will be prepared summarizing any action taken as a result of the internal audit.

4.15 Management Reviews

4.15.1 GMD and CCL Reviews

Calibration services are included in GMD Science Reviews, conducted every 4-5 years. These reviews, with reporting to upper NOAA management, cover all aspects of GMD and are used to assess the performance and relevance of GMD activities with respect to the laboratory mission. Activities of the WMO/GAW CCLs are also discussed at WMO/IAEA Carbon Dioxide, Greenhouse Gas and Related Measurement Techniques (abbreviated as GGMT) meetings (held approximately every 2 years). Recommendations for improving CCL functions are made at GGMT meetings. Technical aspects of calibration and measurement are also considered during AGAGE (Advanced Global Atmospheric Gases Experiment) meetings, in which GMD staff members often participate.

GMD will perform annual management reviews to assess the performance of calibration efforts. The review shall take account of suitability of policies and procedures, results from audits, customer feedback, changes in volume and type of work, corrective and preventive actions, complaints, feedback from staff, feedback received at GGMT meetings, resources, and training.

4.15.2 GMD-Level Assessments

Quality System reviews, conducted by assessors who are external to GMD, are organized by the GMD Quality Manager and carried out at least once every 5 years.

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5.0 Technical requirements

5.1 General

Factors that contribute to the quality of the reference materials and calibration services are documented in various technical procedures and publications. Factors include methods and method validation, environmental conditions, and measurement traceability.

5.2 Personnel

An updated list of Technical Leads for calibration and reference material activities is located <u>in</u> the Appendix. Personnel performing tasks related to the preparation and analysis of reference materials are deemed qualified based on GMD hiring and personnel evaluation procedures. Yearly evaluations of the performance of personnel involved in the production of reference materials will be conducted through the annual performance management cycle and as-needed to address deviations in section 4.11 and 4.14. Personnel hired through the University of Colorado, Cooperative Institute for Research in Environmental Sciences (CIRES), must possess a university degree as per CIRES policy (http://www.colorado.edu/vcr/hr/about). Contractors generally will not assist in the actual production of standards, but may be needed in an ancillary support role such as purchasing vetted commercially available supply inputs.

Decisions for hiring and level of experience required are made at the group leader level, with input from additional staff. Training normally takes the form of mentoring, involving technical leads and analysts. Additional training needs or requests (goals) may be brought to the attention of technical leads and discussed at group leader level. Technical and managerial training records are stored on the GMD server at //emc3/CCL. To aid in succession planning, each analyst should be trained on the operation of at least one other instrument. Training associated with safe laboratory practices is recorded at the division level for all GMD staff members on an individual basis

5.2.1 Planning and control of reference materials

Planning and control of each project involving reference materials or calibration is managed by the project coordinator (PC). Prioritization of reference material preparation and calibration is the responsibility of the PC in collaboration with technical leads and, if necessary, higher levels of GMD management. A first-come first-serve priority system is generally recommended, but priorities can also be set considering customer needs, storage and handling of materials, material preparation, and the availability of resources. Each TL (or designee) is responsible for managing the workload for a particular calibration service. Conflicts in scheduling or priorities are to be resolved at the TL or GL level.

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The PC makes sure all staff involved with the measurement process (work plan) are aware of the requirements specified in the MOU. As analyses are completed, results added to the database or sent to the PC. The PC monitors results to detect any apparent discrepancies or deficiencies. Apparent problems are discussed with the analysts or TLs. Appropriate actions are documented, where necessary.

5.3 Accommodation and environmental conditions

- 5.3.1 GMD, in collaboration with the General Services Administration (GSA), is responsible for assuring that environmental conditions do not adversely affect the quality of measurement services. Critical environmental conditions (i.e., those that could adversely affect measurement results if varied from those required) and the procedures for preventing them from compromising the quality of results are detailed in the Technical Procedures. The analyst determines whether requisite environmental conditions are met for a specific calibration service. Any stoppage due to environmental conditions should be documented in project records.
- 5.3.2 GMD analysts monitor environmental conditions and their impact on analytical results. System performance is verified on a routine basis (using control standards, standards with a history of measurement, or by other means), and these data can be used to examine the effects of environmental conditions.
- 5.3.3 Measurement equipment is installed and operated in ways that prevent interferences between electronics. This includes segregation, as needed, from activities that are outside the scope of this manual. Chemicals and other laboratory consumables are stored under the conditions necessary to maintain their stability or integrity and to prevent cross-contamination with other materials.
- 5.3.4 Access to GMD laboratories is controlled by key access for staff. GMD follows site-wide policies related to safety and security for visitors and guests. Access to GMD laboratories, offices, and storage areas is limited to GMD personnel, authorized guests, security, safety, and housekeeping staff. No others may have access without the knowledge of the person responsible for the laboratory, office, or storage area. If necessary to ensure proper system performance and quality, access to certain GMD laboratories may be restricted during certain periods. Use of critical equipment may be restricted as necessary, with management approval.
- 5.3.5 The practice of good laboratory housekeeping is performed in accordance with GMD safety procedures and in the interest of maintaining quality measurements.

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5.4 Measurement procedures and validation

5.4.1 General

Manuals and instructions for equipment should be kept in the laboratory or offices of the analyst or technical lead. Procedures for safe handling of compressed gases and chemicals are available on the GMD web-site. All laboratory staff should be familiar with safe operating and handling procedures.

5.4.2 Selection of methods

Methods described in Technical Procedures are known as GMD methods. GMD methods (or the results thereof) have been presented at WMO/GAW meetings and/or published in the peer-reviewed literature. Major changes in analytical methods, to the extent that the changes affect calibration results, are discussed within the WMO/GAW community. Analysts should use GMD methods unless circumstances warrant a deviation (see 5.4.4). When standard methods, such as those developed by consensus standards development organizations (e.g. ISO), are available, GMD will consider the use of standard methods. Use of standard methods may be discussed at WMO/GAW meetings or through consultation with WMO/GAW personnel.

5.4.3 Laboratory-developed methods

Methods developed in the laboratory and described in Technical Procedures are, for the purposes of this QM, considered GMD methods.

5.4.4 Deviation from GMD methods

Deviations from methods described in technical procedures should be discussed with the customer prior to accepting the calibration work order. If a need for deviation arises after the work order is accepted, the customer should be notified. Some reasons for deviating from GMD methods might include: (a) the gas or sample container differs from what was specified in the agreement, or differs from what is used by other WMO/GAW laboratories; (b) the pressure is too low to apply GMD methods, (c) the requested calibration is outside the range of the WMO/GAW scale, (d) unforeseen circumstances prevent the use of GMD methods. Deviations from GMD methods should be noted in analysis certificates. Any additional uncertainties associated with a deviation of the method should be communicated to the customer.

5.4.5 Validation

GMD critically evaluates all methods used for official measurements. GMD methods are documented and evaluated through any of the following ways: (a) peer-review literature, (b) scientific meetings, including WMO/GAW meetings, (c) WMO/GAW reports, (d) NOAA

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technical reports. It is not necessary to demonstrate and document every aspect of method validation at every use of the method. The GMD analyst may use documented evidence from prior applications of the method to demonstrate validity. For example, the working range of the method may have been demonstrated in a published paper. Methods that have yet to be published may be validated by comparison to existing methods, or by comparison of existing standards. Methods are validated over a specific mole fraction range corresponding to the WMO/GAW scale. Method validation may include:

- testing selectivity and specificity
- testing valid range
- evaluating sources of bias
- evaluating a response function (linear, polynomial, etc.)
- demonstrating reproducibility over a specified range or at a specified mole fraction
- routine monitoring of control standards

5.4.6 Estimate of uncertainty

All analysis values reported in analysis certificates, or in association with official measurements, are accompanied by quantitative statements of uncertainty. Measurement results without uncertainties shall be explicitly labeled in the certificate as information values. Details of the measurement uncertainty assessment are contained in the TP-level documents, supplemental documents, or in published literature. GMD may receive guidance from the WMO/GAW community on recommendations for estimating uncertainties. The meaning of uncertainty estimates shall be explicitly stated.

5.4.7 Control of data

Procedures for checking calculations, verifying data transfer, storing data, and evaluating associated data processing software are the responsibility of the technical leads and are included in the TP documents. Where possible, when new or upgraded instrumental, operational, and/or computational software is first used, tests are performed to assure accurate results. Official updates, upgrades, and new versions of commercial software are excluded from this requirement. For this purpose, a data set or sample previously run on the prior software or instrument may be run and results compared. If a new instrument is developed, the older instrument is not retired until a suitable comparison is completed. The instrument used in each calibration is recorded as part of the data record.

All computer systems involved in the technical portion of providing measurement services, such as data acquisition and analysis, will be appropriately protected to prevent compromises in confidentiality, integrity, and availability. GMD computer systems used in data collection, processing and dissemination comply with all federal government requirements, including the Federal Information Security Management Act (FISMA, 2002).

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5.5 Equipment

Equipment used by GMD for calibrations is used not only for services described in this QM, but also for internal calibration critical to GMD's mission. Test equipment that influence certified values must have a calibration schedule and be properly maintained. If a calibration schedule is not recommended by the manufacturer, it is left to the technical lead to determine the calibration schedule. The schedule should be based on observed (or estimated) rates of change and the effect that these changes have on the results. Between calibration periods, function checks should be performed to ensure that the equipment is performing properly (see Technical Procedures). If there is evidence that a piece of critical equipment is not performing properly, the TL should be notified. Calibrations that depend on that piece of equipment should be postponed until the problem is fixed.

5.6 Traceability

Routine calibrations are performed using instruments designed for this purpose. These instruments are calibrated against compressed gas standards of known mole fraction (verified by gravimetrically-prepared standards, or manometric measurement). Traceability is established through an unbroken chain of comparisons. Measurements are traceable to SI units temperature, mass, length, pressure, and/or amount of substance fraction (O_2 in O_2). All SI units are traceable to NIST, either through calibration by NIST, or through an accredited facility. Uncertainties supplied by accredited facilities are such that direct calibration by NIST is not necessary.

5.6.1 Reference standards

Devices and materials critical for maintaining traceability are calibrated by accredited calibration and testing laboratories (see TP_primary_manometer.docx and TP_primary_gravimetry.docx). Intermediate checks are performed as needed, through use of "control" units or intermediate standards.

5.6.2 Transport and storage

The integrity of devices and materials critical for maintaining traceability is maintained through proper handling and storage of such items.

5.7 Sampling

In general, GMD does not calibrate sub-samples of a reference material in lieu of analyzing the reference material itself. In some cases, analysis of a sub-sample may be requested by the customer and these are handled on a case-by-case basis. This would normally be done for quality control purposes and would not be considered an official calibration.

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5.8 Handling of calibration items

- 5.8.1 GMD is committed to the safe and secure handling of calibration materials.
- 5.8.2 Gas cylinders are identified by stamped serial number. This number is used for all references to a particular calibration project, including data stored in the database. A "fill code" is used to designate different fillings of the same cylinder. A calibration project (cylinder(s)) is tracked through different measurement stages through software designed for this purpose, and by attaching a paper work order to the cylinder. Each analyst initials the work order and records the date his/her calibration responsibilities have been completed.
- 5.8.3 The PC is responsible for working through all abnormalities that might occur during preparation and calibration stages.
- 5.8.4 It is GMD policy to store cylinders and other materials for calibration in a secure environment. It is the responsibility of the TLs and analysts to ensure that gas use during the calibration process is not excessive. In some cases a brass GCA-590 plug is used to ensure that cylinders are not "blown down" during transport. The PC should report any mishandling to the customer. Reparations (if warranted) are handled on a case-by-case basis.

5.9 Assuring quality of calibration results

Quality assurance is a vital part of the GMD calibration program. GMD uses a number of methods to ensure that instruments are performing properly and that calibration results are valid. Methods include analysis of control standards, controlled testing, re-testing over a period of time, and inter-laboratory comparisons. Specific methods are described in TPs.

5.10 Reporting results

Certificates are issued for certified reference materials and calibrations of customer-supplied reference materials. Certificates should contain the following information:

- 1. title of document
- 2. name and address of laboratory performing measurement
- 3. general description of the material
- 4. unique identification of report
- 5. method used
- 6. items tested
- 7. results (including scale name or identifier)
- 8. uncertainty estimates
- 9. statement of traceability
- 10. hazardous information

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11. name of person authorizing report

5.10.9: Amendments to certificates

Analysis results for reference materials are available on-line, referenced by cylinder serial number. Web-based access of results has been endorsed by WMO/GAW. In cases where technical issues or approved scale changes might necessitate data reprocessing, with a possible change in a result, customers will be instructed to check the web-based database for updates (amended certificates will not be issued).

6.0 Appendix

6.1 Abbreviations not listed in section 3.0

AGAGE	Advanced Global Atmospheric Gases Experiment
CCL	Central Calibration Laboratory (Defined role in WMO/GAW network)
CGA	Compressed Gas Association
DOT	Department of Transportation (USA)
ESRL	Earth System Research Laboratory
GGMT	Greenhouse Gases and related tracer Measurement Techniques, formerly referred
	to as Meeting of Experts on CO ₂ and related Tracer Measurement Techniques
GMD	Global Monitoring Division (formerly Climate Monitoring and Diagnostics
	Laboratory)
ISO	International Organization for Standardization
NMI	National Metrology Institute
OAR	Oceanic and Atmospheric Research
WMO	World Meteorological Organization

6.2 Personnel

Responsibility	Name
Quality Manager	Russell Schnell (GMD Deputy Director)
Group Chief (Greenhouse Gas Reference Network)	Pieter Tans
Group Chief (Halocarbons &other Atmospheric Trace Species)	James Elkins
Technical Lead CO ₂	Pieter Tans
Technical Lead CH ₄	Ed Dlugokencky
Technical Lead CO	Paul Novelli
Technical Lead N ₂ O	Brad Hall
Technical Lead SF ₆	Brad Hall
Technical Lead Reference Materials	¹ Duane Kitzis

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Analyst Andrew Crotwell
Analyst Patricia Lang
Analyst Thomas Mefford
Analyst Michael Rhodes
Programming Kirk Thoning
Programming Ken Masarie
Programming Dan Chao

Notes: Technical Leads may also perform Analyst duties. ¹Primary project coordinator. ²Deputy project coordinator.

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